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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,626	04/09/2004	Michael G. Mulkerrin	ABGENIX.043A	8933
20995 7590 03/08/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER MEAH, MOHAMMAD Y	
			ART UNIT 1652	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		03/08/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/08/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No.	Applicant(s)	
	10/821,626	MULKERRIN ET AL.	
	Examiner	Art Unit	
	Mohammad Meah	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-15 and 59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-15, 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 5-15 and 59 were examined in the previous action. With supplemental amendment of this application, the applicant, on dates 12/22/06, amended claims 5-6 and cancelled claims 1-4 and 16-29. Therefore claims 5-15 and 59 are for further examination.

35 U.S.C 112 Rejection***35 U.S.C 112 2nd paragraph rejection***

I. Rejection of claim 5 under 35 U.S.C. 112, 2nd paragraph is withdrawn after amendment of the claim.

II. Written Description requirement

As described in the prior action, claims 5-15 and 59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to catalytic antibody. The specification discusses making antibodies in general and discloses a method of making the compound shown in claim I. There is no disclosure that the antigen made has ever been used to make antibodies and especially not catalytic antibodies. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed

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invention.

Applicants arguments at page 5-6 of their amendment against rejection of claims 5-15 and 59 under 35 U.S.C. 112, first paragraph written description are acknowledged but is not found persuasive because these claims are directed to catalytic antibody for a hapten for which no disclosure of making said catalytic antibody is given in the specification. Applicant actually did not make any catalytic antibody using their hapten, there is uncertainty whether transition state analogue of their hapten mimic the transition state analog of the asparagines deaminase. Immuno-activity more even catalytic activity of an antibody depend on the structure of the hapten, a subtle change in its structure may make enormous variation in the catalytic activity of the antibodies that it produce(Mader et al 1997). In generating antibodies against an antigen, the immune system makes multiplicity of proteins that bind the hapten, to find which of these enormous numbers of antibodies that is catalytic needs prior knowledge of the specific structure of the hapten that mimic best with the transition state structure of the enzymatic reaction itself (Mader et al 1997). Benkovic et al. (US pat 5439812, table 1) shows that among 30 antibodies arise from cyclic phosphinate transition state analog of Asp deamidase (it have some similarities with applicants hapten) only 5 shows very feeble catalytic activities. Therefore, as discussed in the written description guidelines the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a

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combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species, which are adequately described, are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. Since the specification neither teaches the isolation nor characterization of any catalytic antibody of the hapten, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

III. Enablement requirement

Claims 5-15 and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As discussed in the prior action the instant specification does not disclose that any antibodies have been made using the structure shown in claim 1 as an antigen and certainly does not disclose that any antibodies that were catalytic have been made. While it is acknowledged that most chemical compounds can be used to make an antibody, especially if it is attached to a carrier molecule, the making of antibodies that are catalytic is an unpredictable art.

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Applicants' arguments, on page 6 of their amendment, against rejection of claim 5-15 and 59 under 35 U.S.C 112, first paragraph enablement are acknowledged.

Applicants argue that

(a) Applicant made the antigen and attaching the said antigen to a carrier molecule is enabled since art of conjugating a hapten to carrier molecule is well known.

(b) Applicant argue that making antibodies from immunoconjugate are known in prior art, an artisan is enabled using the common knowledge of molecular biology to make and use the invention recited in these claims based on the prior art knowledge.

It is not found persuasive because specification does not disclose any antibodies have been made using the structure shown in claim 1 as an antigen and certainly does not disclose that any antibodies that were catalytic have been made. As discussed in the prior action making of antibodies that are catalytic is an unpredictable art. While eliciting immune response using antigen and making antibody is well known to the skilled artisan making catalytic antibodies and selecting an antibody which is catalytic requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the enormous numbers of antibodies have the claimed property. Since applicant does not make any catalytic antibody for their hapten, having no example of provided for a catalytic antibody one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute **undue** experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the

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experimentation should proceed. Such guidance has **not** been provided in the instant specification.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Mohammad Younus Meah, PhD

Examiner, Art Unit 1652

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